

**Transcript for FDA's Media Briefing on its
Draft Guidance on Judicious Use of
Medically Important Antimicrobials in Food-Producing Animals
June 28, 2010**

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode. After the presentation today we will be pausing to take questions.

During the question and answer sessions if you'd like to ask a question the command to do so will be star then 1 on your touch-tone phone.

Today's conference is being recorded. If you have any objections you may disconnect at this time. And now I'd like to introduce your host for today's call, Ms. Siobhan Delancey from the FDA Office of Public Affairs. Ma'am, you may begin.

Siobhan Delancey: Thank you very much. Welcome ladies and gentlemen. This is an FDA teleconference for credentialed media to get information on the FDA's draft guidance on the judicious use of medically important antimicrobial drugs in food producing animals. This briefing is for credentialed media only.

Our speakers today are Dr. Joshua Sharfstein, Principal Deputy Commission of Food and Drug and Dr. Bernadette Dunham, Director of the Center for Veterinary Medicine at the FDA.

We also have technical experts standing by to answer your questions: Dr. William Flynn, Senior Advisor for Science Policy at the Center for Veterinary Medicine and Dr. John Clifford, Chief Veterinary Officer at the United States Department of Agriculture.

After the speakers make brief remarks, we'll move to a question and answer segment. Reporters will be in a listen-only mode until we open the call for questions.

When asking a question please state your name and your affiliation. Please limit yourself to one question and one follow-up so we can get to as many questions as possible.

The news release for this announcement has been sent to reporters on our media list as well as posted to FDA's Website at www.fda.gov. I'll now turn the call over to Dr. Sharfstein.

Joshua Sharfstein: Thank you Siobhan. I'm Josh Sharfstein, the Principal Deputy Commissioner at the Food & Drug Administration. Thank you for joining the call.

Antimicrobial agents have been used in human and veterinary medicine for more than 50 years with tremendous benefits to both human and animal health.

However, because bacteria are so good at becoming resistant to antimicrobial drugs, it is essential that such drugs be used judiciously to delay the development of resistance.

Misuse and overuse of these drugs contribute to a rapid development of resistance.

After several decades of successful antimicrobial use, we are seeing the emergence of multi drug resistant bacterial pathogens which are less responsive to therapy.

Antimicrobial resistant bacterial population are emerging due to the combined impact of various uses of antimicrobial drugs including their use in both humans and animals.

The draft document FDA is issuing today summarizes the number of important reports on the use of antimicrobial drugs in animal agriculture and the impact of such use on antimicrobial resistance.

Based on our review, FDA believes the overall weight of evidence available to date supports the conclusion that using medically important antimicrobial drugs for production purposes is not in the interest of protecting and promoting the public health.

The draft document provides a framework for policy development regarding the appropriate or judicious use of medically important antimicrobial drugs and food-producing animals.

Developing strategies for reducing anti-microbial resistance is critically important to protect the public health.

We recognize that collaboration involving the public, the public health, the animal health and animal agriculture communities on the development and implementation of such strategies is needed for us to move forward.

We also recognize the importance of assuring that such strategies are feasible and that the health needs of animals are addressed.

In order to preserve the effectiveness of these important antimicrobial drugs, we simply must use them as judiciously as possible. And today's draft

guidance provides general principles and key first steps for achieving that goal in animal agriculture.

I now would like to turn to Dr. Bernadette Dunham, the Director of the Center for Veterinary Medicine in FDA.

Bernadette Dunham: Thank you Dr. Sharfstein. As most of you are aware, the topic of antimicrobial resistance relative to animal agriculture has been debated for a long time with some very smart and very passionate people on all sides of the issue.

We believe that today's draft guidance represents a balanced approach to this growing problem.

FDA is committed to working with animal drug sponsors, the veterinary and public health communities, the animal agriculture community and all other interested stakeholders in developing a strategy to address antimicrobial resistance concerns in a manner that is protective of both human and animal health while minimizing adverse impacts on animal health and disruption to the animal agriculture industry.

The draft guidance discusses FDA's current thinking on ways to assure that medically important antimicrobial drugs are used judiciously in animal agriculture including two general principles.

First that the use of medically important antimicrobial drugs in food producing animals should be limited to those uses that are considered necessary for assuring animal health.

FDA believes that the use of medically important anti-microbial drugs in food animals for product purposes such as growth promotion and feed efficiency represents an injudicious use of these drugs.

And the second principle is that the use of medically important anti-microbial drugs in food producing animals should be limited to those uses that include veterinary oversight or consultation.

Veterinarians can play a critical role in the diagnosis of disease and in the decision-making process related to instituting measures to treat, control or prevent disease.

As I've said many times, using medically important antimicrobial drugs as judiciously as possible is key to minimizing the development of resistance and preserving the effectiveness of these drugs as therapies for both humans and animals.

And while FDA acknowledges the efforts to date by various veterinary and animal producer organizations to institute guidelines for the judicious use of antimicrobial drugs, we believe additional steps are needed to have a real impact on this problem.

So we ask that our animal drug sponsors, the veterinary and public health communities, the animal agriculture community and all other interested stakeholders please consider our ideas as outlined in the draft guidance and let us know what you think. We look forward to working with all of you as we move forward to address this very important issue. Thank you.

Siobhan Delancey: Thank you Dr. Dunham. At this time ladies and gentlemen, we'd like to begin the question and answer period of the briefing. The operator will take the first question.

Coordinator: Yes ma'am. If you'd like to ask a question at this time, please press star 1. You'll be prompted to un-mute your phone and record your name as your name is required to introduce your question.

Our first question today comes from Sally Schuff with Foodstuffs. Ma'am your line is open.

Sally Schuff: Yes, thank you. This is Sally Schuff at Feedstuffs. My question I think for Dr. Sharfstein is what (weight) guidance in - have right now?

Is there a timeframe for implementing it? Does it have the force of regulation? Is there a rulemaking coming? What is the legal process at this point?

Joshua Sharfstein: So this document is a statement of the FDA's approach to the problem or assessment. It summarizes some - you know, very important public health reports. But it's not a regulation or a proposed regulation.

I think that this could, you know, by establishing the basic principles that we would use it could very much influence our regulatory approach to this.

And we're interested in getting comments from people on how these principles could be implemented. But in itself it is not a rule-making document.

Sally Schuff: And if I might ask a follow-up on that. I apologize because I haven't seen the press release yet. It hasn't come in.

Is there a public comment period on this draft guidance?

Joshua Sharfstein: Yes there is. And we're very much...

William Flynn: (Unintelligible) encouraging.

Joshua Sharfstein: ...yeah. There's a 60 day comment period on this draft document. That was Dr. Bill Flynn. And we're very much interested in what - people's comments particularly around how we can feasibly achieve these goals.

Sally Schuff: Thank you very much.

Joshua Sharfstein: And...

Coordinator: Our next question...

Siobhan Delancey: Thank you for your question.

Coordinator: Our next question comes from Gardiner Harris of the New York Times. Your line is open.

Gardiner Harris: Hey, help me understand. It sounds like you're going to limit their - I guess I'm - as I understand it there are three uses of antibiotics in feed animals treatment, prevention and growth promotion.

And you're going to limit the - or try to eliminate the 1/3 of those. Do you have any idea what share of the use of medically important antibiotics comes from that third portion? And does it - has there been some experience?

I think in other countries that by limiting the third portion you simply grow the other two portions. Thanks?

William Flynn: Yes, this is Bill Flynn from FDA. We don't have a specific - there's specific numbers to share, available to share it to you. That - but the extent to which it's used for that purpose it does represent a significant proportion of use. But we don't have good data to define exactly what that would be.

Joshua Sharfstein: And then your second question Gardiner?

Gardiner Harris: Just it sounds like what you're hoping to do or what you're saying in this...

Joshua Sharfstein: Oh I see.

((Crosstalk))

Gardiner Harris: ...is that you would like to eliminate that form of use. But will that necessarily sort of lead to the expansion of the other two uses?

Joshua Sharfstein: Oh wait, no, no. I got it. This is Josh Sharfstein. I think that the principles here are that we have to reduce use overall just like in human medicine in order to have the effect that we want on antimicrobial resistance.

And it - the judicious use concept applies across all types of uses. For production uses we think the judicious thing is not to use them in that way.

For prevention uses there's some discussion of that in the draft guidance which says that it should be very clearly resting on a very strong scientific foundation.

And then even for treatment uses we think it's very important just like in human medicine that the animal agriculture community identify narrowly where medications should be used for treatment.

And, ultimately, you know, success is going to be seen in the, you know, data about resistance patterns.

But goal is to reduce use overall. And it's not just limited to this part. And I think that's one of the reasons why, you know, we want to establish these basic principles before moving forward.

Gardiner Harris: Thanks so much.

Coordinator: Our next question comes from Meredith Wadman of Nature Magazine. And your line is open.

Meredith Wadman: Hi. I'm wondering if you can give an example of a precedent where a guidance which is non-binding on industry has nonetheless been taken up and really implemented?

In other words I'm a bit skeptical that, you know, just telling industry that we think this is what you should do, actually makes them do it.

And I'm looking for, you know, based on your historical knowledge what - the kind of impact that - the guidances that stop short of regulation of have in past maybe in...

Joshua Sharfstein: Right. Thanks Meredith. This is Josh Sharfstein. I think we should be clear about this. We're not expecting people to pick up this guidance and change their practice tomorrow.

This is the first, you know, step in FDA establishing the principles from which we could then move if necessary to other mechanisms of oversight such as regulation.

So I don't think that's the right standard to hold this to. This is really a document that doesn't tell people what to do through a guidance. It establishes principles.

And now we're seeking comment on how to achieve those principles. And then we have a whole bunch of other tools that we could if necessary bring to bear on that.

Meredith Wadman: Thanks.

Coordinator: Our next question comes from Elizabeth Weise of USA Today. Your line is open.

Elizabeth Weise: Thanks so much for taking my call. I had a question and a follow-up. The first question is you say medically important antimicrobial is used in humans. And I'm wondering can you tell us which antimicrobials you're thinking of?

And then those antimicrobials often exist in broad categories. And I know sometimes a certain formulation will be used in humans and something chemically quite similar but with a different name will be used in animals. How broadly are you going to define that?

Joshua Sharfstein: Well I think I'm going to turn it to Bill Flynn in a second for - to answer this. But I think for medically important we're really talking about the whole class

of drugs that if there's a class of medications that's used in humans, then that class in animals counts as medically important.

It doesn't matter whether the specific tetracycline erythromycin is used also. It's the general class. But Bill is there anything you want to add?

William Flynn: Right. And then just to add right, to everything we're talking about here this morning is primarily focused on those drugs that, you know, we've called medically important which essentially means they're important therapies in humans for treating bacterial infectious diseases.

And so there's numerous, you know, different classes of drugs that might fall into that category.

Joshua Sharfstein: But it's really defined by class, not by individual. But...

Elizabeth Weise: Could you give some names just so that - because, you know, readers know what drugs they might have taken. And I'm trying to get a sense of, you know, would it be something that somebody who'd been on antibiotics in the last year say oh yes, I know which one that is?

Joshua Sharfstein: Yes there's - you know, this is not an all-inclusive list. But I mean there are drugs like the penicillins or the tetracycline classes or the macrolide classes of antibiotics or - have - all have important uses in - for therapeutic purposes in humans.

Elizabeth Weise: Okay, thank you.

Coordinator: Our next question comes from Mary Claire Jalonick with the Associated Press. Your line is open.

Mary Clare Jalonick: Hi, just was follow-up on some of the other questions. But you all are being a little bit vague about whether you will ultimately issue regulations. I mean is this - would you say this is sort of a warning to the animal agriculture community if things don't change and you don't see a reduction in those numbers of resistance patterns that you all might eventually mandate it?

Joshua Sharfstein: Well this is Josh Sharfstein. I think, you know, we have to take one step at a time. We want to really establish the principles that are the basis of our assessment and then we - we'll go from there.

One of the things we're doing is getting comments on how things could be accomplished and there are different mechanisms.

We have the regulatory mechanisms and the industry knows that. But we are also interested in what things can be done just voluntarily that they would do them. And I think it'll be interesting to see how the industry responds to this and how - what direction their comments take.

So I mean we're not handcuffed to the steering wheel of a particular strategy at this point. We really want to understand what people think. And but we're also - I'm not ruling out anything that we could do to accomplish these important public health goals.

Siobhan Delancey: Thanks. Did you have a follow-up?

Mary Clare Jalonick: No, that's it. Thank you.

Coordinator: Our next question comes from Chuck Abbott with Reuters. Your line is open.

Chuck Abbott: Good morning. This is sound like (very clear) and I, you know, had our brains together (unintelligible) (just) you can just walk us through the timeline of what will happen beginning today.

You said there's a 60 day comment period. What happens after the 60 day comment period?

Bernadette Dunham: This is Dr. Dunham. After the 60 days we'll have an opportunity, FDA will take a look at those comments and we will be able to go through and see the various ideas that have been put forth from all of the various impacted stakeholders.

And that'll give us an opportunity then to sit down and possibly have some workshops. At the same time from there we may be able to then put forward some next steps that everybody would probably embrace and agree on.

And that can come out again as another document that we will prepare for further comment. But it's an opportunity to team tag and work together through this with what we heard a minute ago from Dr. Sharfstein.

There won't be one size fits all. I think there's going to be a number of different solutions oftentimes case by case that will allow us to work together to move this one forward in the right direction.

So after we've done that we'll see just what those next steps are. At the same time working very closely with the pharmaceutical companies we'll have an opportunity to see where they will also work with us.

And this will be an opportunity to see this in fact take place working closely to clarify drug claims and the use of these very important antimicrobials appropriately.

Joshua Sharfstein: Now I would just add that this is, you know, very much - the significance of this document is that it encapsulates the agency's thinking of this as a public health issue.

And, you know, that becomes then the foundation for the next steps.

Chuck Abbott: Okay well it's like - I don't - well I was going to say I don't want to belabor the point but maybe I am and it doesn't matter.

So well we could be - this process could take what, years into the future?

Joshua Sharfstein: Well I think that- this is Dr. Sharfstein. There are many aspects of this process. I personally would not like to see it take years.

You know, I think we believe this is a public health issue of some urgency and that's really what we're stating in this document.

And we're looking for different paths where we can see progress soon.

Bernadette Dunham: This is Dr. Dunham. It's an opportunity as I mentioned a minute ago that this is something we want very much to move forward.

I think everybody's engaged. It'll be very, very important that we work closely with the veterinary community because again this is an opportunity to phase in more of the oversights that we do need from the veterinarians. And

that also is something that we'll be receiving feedback from and an opportunity to make that happen sooner.

Siobhan Delancey: Thanks Dr. Dunham. We're going to have time for just two more questions.

Coordinator: Our next question comes from Alicia Mundy with the Wall Street Journal. Your line is open.

Alicia Mundy: Hi. Thank you again for taking my question. You know, going back as far as 1997, the FDA had said it was trying to get the animal food, the animal feed makers to limit the use of penicillin and tetracycline and we're still here today.

And in 2008, you know, the FDA was going to implement a ban that it had carefully thought out over two years of cyclosporins in feed and then ended up reversing that.

It almost seems that what you're doing today is starting back at square one on the issues that led to the cephalosporin ban that ultimately wasn't there.

Are we starting over and what is different about today?

Joshua Sharfstein: Alicia there are a few things that are different and I think we should piece through that. I'm going to ask Bill Flynn to explain that this is a very different issue than what was at stake with the cyclosporins. We're going to do that first.

William Flynn: Right. First we did issue a document probably a year ago or so related to the extra label use of a cephalosporin class of drugs which is a therapeutic - a

drug that's used for therapeutic purposes in animals. It's an injectable product. It's not used in feed or water.

And that was a process that we initiated to look at because of concerns about the impacts of off label. These are extra label off label uses might be happening, contributing to resistance.

The agency did issue that order and as part of that process received public comments on that order. We've in response to the comments we received, we withdrew the order in order to give us additional time to review those comments and consider how to move forward on that document.

Joshua Sharfstein: Right. I think the key point though is that that's a separate issue...

William Flynn: Separate issue.

Joshua Sharfstein: ...that this is about the judicious use of antimicrobials focusing on production uses. And that's about the use of a therapeutic use in a different class of medications. So those are on parallel tracks.

I think there - oh do you want to follow-up on that...

((Crosstalk))

Alicia Mundy: Yes. I mean yes, I know that the cephalosporins were supposed to be, you know, to deal with things like the respiratory diseases that you didn't want, you know, breaking out and taking down, you know, an entire chicken farm.

But even though they're not exactly the same, you're still dealing with the overuse of antimicrobial products in, you know, in animals that ultimately get

into the system. And, you know, there hasn't been - it doesn't appear from an outside perspective that there had been much movement on either way whether it was the penicillin and tetracycline that you asked for in '97 or the cephalosporin because there was such pushback from the - you know, the stakeholders on the other side.

So that's why I'm - that's why to me they seem to be - you know, there seems to be a certain déjà vu aspect that I'm just trying to ask you to clarify.

Joshua Sharfstein: Sorry. So let's separate out the two things. On the cephalosporin, that is handled separately. It's not covered in this document at all.

We have to finalize that effort. But that's - but this isn't like related to that. It's not like a step back from that or a step forward on that. It's just a different thing because it's a different type of use of antimicrobials. It's obviously connected because they're both related to resistance.

On the 1997 I'm not sure what you're referring to. In 1977 FDA proposed to withdraw the new animal drug approvals for set therapeutic uses of penicillin and tetracyclines in animal feed. I don't know, you were referring to the 1977 action?

Alicia Mundy: The 1977, yes.

Joshua Sharfstein: So here we are in 2010 and there's been a lot of science done since then. And FDA has not had the position that over the last couple decades that we're articulating in this document.

And it's based on a whole range of reports that have happened and really a consensus that has emerged really over the last maybe ten to 15 years in the public health community.

And so we're - this is actually, you know, a step forward in the modern era towards the principles that would then be the foundation for a range of different actions by different people to protect the public health.

Alicia Mundy: Okay.

Siobhan Delancey: And I think we're going to have to go to our last question because we're running out of time.

Coordinator: Our final question comes from Ben Moscovitch with Inside Health Policy. Your line is open.

Ben Moscovitch: Hi, thanks for taking my call. Does FDA believe that it has the statutory authority to dictate the use of antibiotics through a rule-making process? And would statutory authority in this area help the agency move forward?

Joshua Sharfstein: This is Dr. Sharfstein. I'm not quite sure I understand your first question because they're different mechanisms that FDA has under the law, not just rulemaking for acting in this area.

This document is not about that though. This document is about the principals that we would use as we assess the various ways that we could accomplish the goal.

And it's significant because FDA is stating very clearly that certain uses are not judicious, that veterinarian oversight needs to be present and that this is in fact a very important public health issue.

So we're sort of setting the foundation from which we could then talk about regulations, talk about legislation. This is sort of the basic principles in this area which have not really been articulated by the agency before.

Siobhan Delancey: Okay thank you ladies and gentlemen. This concludes today's media teleconference. Thank you for your participation.

A replay will be available in about an hour and will be available for the next seven days.

If you have follow-up questions please call the FDA Office of Public Affairs at 301-796-4540. Thank you very much.

Coordinator: This concludes today's conference. You may disconnect at this time.

END